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March 15, 2019

BY E-FILE AND HAND DELIVERY

The Honorable Colm F. Connolly
United States District Court of Delaware
844 North King Street
Wilmington, DE 19801

**REDACTED -
PUBLIC VERSION**

Re: *Genentech, Inc. v. Amgen Inc.*, C.A. No. 17-1407-CFC
(Consolidated)

Dear Judge Connolly:

I write in response to the Court's Order, D.I. 300. Amgen understands that Plaintiffs seek modification of the Protective Order to file "the Complaint provided by [Plaintiffs] to Amgen on January 28, 2019" (the "Proposed Complaint"). D.I. 291, at 2. The Proposed Complaint alleges infringement against two different activities: (1) Amgen's manufacture of Mvasi™ [REDACTED] and (2) Amgen's manufacture of an unrelated product, [REDACTED] which has nothing to do with Mvasi™, this case, or Amgen's Biologics License Application ("BLA") No. 761028.

First, as to the [REDACTED] allegations, Plaintiffs take the position that Amgen's [REDACTED] does not "aris[e] from Defendant's filing of [BLA] No. 761028." Under Plaintiffs' view, the [REDACTED] triggered an independent BPCIA action divorced from BLA No. 761028. *See, e.g.*, D.I. 291, at 1 ("Genentech . . . advised the Court that the [REDACTED] would trigger a new lawsuit once the parties completed the 'patent dance' procedures set forth in 42 U.S.C. § 262(l)"); *id.* at Ex. 2, ¶¶ 3, 17, 19, 40. Under Plaintiffs' view that the allegations do not arise from BLA No. 761028, filing the Proposed Complaint would violate the Protective Order because it is based on (and extensively refers to) Amgen confidential information produced in this case.

However, the Court need not decide whether the [REDACTED] "aris[es] from" the original Mvasi™ BLA to resolve this dispute. Plaintiffs simply do not need to modify the Protective Order to pursue claims for infringement against Amgen's [REDACTED] because the parties are already litigating those issues in this case. Over the last approximately eleven months, Plaintiffs have pursued (and received) extensive discovery regarding [REDACTED]

The Honorable Colm F. Connolly
Page 2

_____ If Plaintiffs want to assert against Amgen the two patents they added to the Proposed Complaint, they should have, among other things, sought leave to amend the complaint *in this case* under Fed. R. Civ. P. 15 and shown “good cause” under the Scheduling Order. D.I. 295 at 1-2.

Second, the Proposed Complaint alleges infringement against Amgen's [REDACTED] product, which is unrelated to Mvasi™. Manufacture of [REDACTED] unquestionably does not “aris[e] from Defendant’s filing of [BLA] No. 761028.” Because the [REDACTED] allegations are based on Amgen confidential information produced in this case, the protective order bars Genentech from using that information for its Proposed Complaint. *See, e.g.*, D.I. 291 at Ex. 2, ¶237.

Respectfully,

/s/ Melanie K. Sharp

Melanie K. Sharp (No. 2501)

MK S

cc: Michael P. Kelly, Esquire (by e-mail)
Daniel M. Silver, Esquire (by e-mail)

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC. and CITY OF HOPE)

Plaintiffs,

v.

AMGEN INC.,

Defendant.

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C. A. No.: 17-1407-CFC
(CONSOLIDATED)

WORD COUNT CERTIFICATION

The undersigned hereby certifies that the foregoing letter contains 398 words in Times New Roman 14-point font, which were counted using Microsoft Word's word count feature.